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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,288	04/13/2005	Richard A. Joseph	NEN-21902/16	4906
37742 7590 01/28/2008 GIFFORD, KRASS, SPRINKLE, ANDERSON & CITKOWSKI, P.C. P.O. BOX 7021 TROY, MI 48007-7021			EXAMINER SISSON, BRADLEY L	
			ART UNIT 1634	PAPER NUMBER
			MAIL DATE 01/28/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,288

Applicant(s)

JOSEPH ET AL.

Examiner

/Bradley L. Sisson/

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12,15-19,21-28 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-12,15-19,21-28 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1, 3-12, 15-19, and 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 and claims 3-12, which depend therefrom, are indefinite with respect to what constitutes the "association." While claim 1 does indicate that the association is "independent" of the type of bond between the oligonucleotide and the label, it is unclear as to just what the oligonucleotide is association with, much less how it is associating. Claims 3-12, which depend from claim 1, fail to overcome this issue and are similarly rejected.

4. Claim 15 is confusing as a result of the phrase "labeled by...an association independent of a dual contribution covalent bond." It is less than clear just what kind of bond exists between the oligonucleotide and the fluorescent compound. Claims 16-28, which depend from claim 15, fail to overcome this issue and are similarly rejected.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 3-12, 15-19, 21-28, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,268,148 (Barany et al.) in view of US Patent Application Publication 2002/0119526 A1 (Zuker et al.) and US Patent 6,444,111 (Montgomery).

9. Barany et al., column 25, disclose a method of detecting oligonucleotide elongation wherein the primer is labeled. The use of a fluorescent label is specifically identified. The means by which the primer is elongated can be a ligase- or polymerase-based assay.

10. Barany et al., do not specifically teach the manner by which the label is attached to the oligonucleotide primer.

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11. Zuker et al., paragraph 0083, teach a plethora of noncovalent means by which a probe or oligonucleotide can be labeled. Such means include ionic, van der Waals, electrostatic and hydrogen bonds.

12. Zuker et al., paragraph 0082, disclose a non-limiting list of labels that can be bound to said oligonucleotide. As seen therein, such labels include fluorescent yes, electron-dense reagents (e.g., metals), enzymes, haptens, proteins, as well as radioactive substances.

13. Zuker et al., paragraph 0117, teach that amplification techniques can be applied to both DNA and RNA. Such a disclosure speaks directly to performing reverse transcription of RNA to as to allow of the amplification of its DNA copy (cDNA).

14. While both Barany et al., and Zuker et al., teach using fluorescently labeled oligonucleotides, they have not been found to explicitly teach using a metal-containing fluorescent compound.

15. Montgomery discloses performing a variety of oligonucleotide elongation reactions wherein fluorescence is generated and platinum is used as a quencher of unwanted, unintentional fluorescence.

16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the oligonucleotide primers of Barany et al., with the method of labeling of Zuker et al., as Zuker et al., teach a multitude of reproducible labeling methods that are applicable to numerous labels. Said ordinary artisan would have also been motivated to have modified the fluorescent label of Barany et al., and Zuker et al., with tat of Montgomery as Montgomery teaches that by doing so unwanted, unintentional fluorescence is quenched, thereby allowing for increased sensitivity.

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17. In view of the explicit motivation and detailed guidance, said ordinary artisan would have had a most reasonable expectation of success.

18. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 3-12, 15-19, 21-28, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,268,148 (Barany et al.) in view of US Patent Application Publication 2002/0119526 A1 (Zuker et al.) and US Patent 6,444,111 (Montgomery).

Conclusion

19. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner
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BLS